IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

GLAXO GROUP LIMITED, Plaintiff and Counterclaim-Defendant, v. CYPRESS PHARMACEUTICAL, INC., Defendant and Counterclaim-Plaintiff.	Civil Action No. 07-6012 Hon. Richard J. Holwell

ANSWER AND COUNTERCLAIMS OF
CYPRESS PHARMACEUTICAL, INC.

For its answer to the Complaint filed by plaintiff, Glaxo Group Limited ("Glaxo"), in the above captioned action, defendant, Cypress Pharmaceutical Inc. ("Cypress"), responds as follows:

THE PARTIES

1. Cypress is without information sufficient to admit or deny the allegations of paragraph 1 of the Complaint and therefore denies the same.

2. Cypress admits that it is a Mississippi corporation and that it applied for and received the authority to do business in the State of New York from the New York Department of State. Cypress also admits that a copy of Cypress' "Entity Information" printed from the New York Department of State website was attached to the Complaint.

JURISDICTION AND VENUE

3. Cypress admits that Glaxo purports to bring this action pursuant to the patent laws of the United States, Title 35, United States Code and 21 U.S.C. §355.

4. Cypress admits that Glaxo purports that jurisdiction and venue are proper in this District pursuant to 28 U.S.C. §§ 1331, 1338(a) and 1391(c).

5. Cypress admits that it is subject to personal jurisdiction in this District.

PATENT INFRINGEMENT PURSUANT TO 35 U.S.C. § 271(e)(2)

6. Cypress admits that United States Patent No. 5,068,249 ("the '249 patent") is entitled "Aqueous Ranitidine Compositions Stabilized with Ethanol." Cypress is without information sufficient to admit or deny the remaining allegations of paragraph 6 of the Complaint and therefore denies the same.

7. Cypress admits that the '249 patent expires on November 27, 2008 and that a copy of the '249 patent was attached to the Complaint. Cypress denies the remaining allegations of paragraph 7 and refers to the '249 patent for the contents thereof.

8. Cypress is without information sufficient to admit or deny the allegations of paragraph 8 of the Complaint and therefore denies the same.

9. Cypress admits that the United States Food and Drug Administration (the "FDA") granted Glaxo pediatric exclusivity extending the term of the '249 patent for six months. Cypress denies the remaining allegations of paragraph 9 of the Complaint.

10. Cypress admits that it submitted to the FDA an ANDA which seeks approval to engage in the commercial manufacture, use, and sale of its Ranitidine Oral Solution USP, 15 mg/ml ("Cypress' product"), and that the ANDA had been assigned number 78-779 (the "ANDA"). Cypress denies the remaining allegations of paragraph 10 of the Complaint.

11. Cypress admits that the ANDA for Cypress' product contains a paragraph IV certification. Cypress denies the remaining allegations of paragraph 11 of the Complaint.

12. Cypress admits that on May 8, 2007, Cypress sent a letter (the "Notification Letter") notifying Glaxo that Cypress had submitted to the FDA an ANDA which sought approval to engage in the commercial manufacture, use, and sale of Cypress' product and that Glaxo received the Notification Letter. Cypress also admits that the Notification Letter stated that no valid claim of the '249 patent will be infringed by the manufacture, use, or sale of Cypress' product. Cypress denies the remaining allegations of paragraph 12 of the Complaint.

13. Cypress denies the allegations of paragraph 13 of the Complaint.

14. Cypress denies the allegations of paragraph 14 of the Complaint.

AFFIRMATIVE DEFENSES

1. The '249 patent is invalid under one or more provisions of Title 35, United States Code.

2. The Complaint fails to state a claim upon which relief can be granted.

3. Cypress denies each and every allegation of the Complaint not specifically admitted, controverted or denied herein.

WHEREFORE, Cypress prays that this Court enter judgment:

A. Dismissing the Complaint with prejudice and denying each and every prayer for relief contained therein;

B. Declaring that the '249 patent is invalid and/or not infringed;

C. Declaring that this case is exceptional under 35 U.S.C. § 285, and that all costs and expenses of this action, including reasonable attorney fees, be awarded to Cypress;

D. Dismissing the Complaint for failure to state a claim upon which relief can be granted; and

E. Awarding to Cypress such further relief as this Court may deem necessary, just, and proper.

COUNTERCLAIMS

For its counterclaims against plaintiff, Glaxo Group Limited ("Glaxo"), counterclaim-plaintiff, Cypress Pharmaceutical Inc. ("Cypress"), avers as follows:

1. This Court has jurisdiction over the subject matter of these counterclaims under 28 U.S.C. §§ 2201, 1331, and 1338.

2. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

3. Glaxo is subject to personal jurisdiction in this District.

THE PARTIES

4. Cypress is a corporation organized and existing under the laws of the State of Mississippi, having a principal place of business at 135 Industrial Blvd., Madison, Mississippi 39110.

5. Upon information and belief, Glaxo is a corporation organized and existing under the laws of England and Wales, having a registered office at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB6 ONN, Middlesex, England.

FIRST CAUSE OF ACTION AGAINST GLAXO
(DECLARATORY JUDGMENT OF INVALIDITY AND NON-INFRINGEMENT)

6. Cypress repeats and realleges the allegations of paragraphs 1-5 as if set forth herein.

7. Cypress has filed Abbreviated New Drug Application ("ANDA") number 78-779, including amendments thereto under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, and sale of Ranitidine Oral Solution USP, 15 mg/ml ("Cypress' product").

8. In its Complaint, Glaxo asserts, and continues to assert, that Cypress has infringed United States Patent No. 5,068,249 ("the '249 patent") by filing the ANDA seeking approval to market Cypress' product.

9. There is a substantial and continuing controversy between Cypress and Glaxo as to Glaxo's assertion of liability under the '249 patent.

10. The '249 patent is invalid under Title 35, United States Code.

11. Cypress' filing of its ANDA did not infringe any valid claim of the '249 patent.

12. Cypress' commercial manufacture, use, sale, or offer to sell Cypress' product for which it seeks FDA approval in its ANDA will not infringe any valid claim of the '249 patent.

WHEREFORE, Cypress prays for relief as follows:

A. That the Court adjudge and decree that any claim of the '249 patent asserted against Cypress is invalid and/or not infringed;

B. That this case be declared exceptional pursuant to 35 U.S.C. §285, and that the Court award Cypress the costs of this action, including reasonable attorney fees; and

C. That the Court order such other and further relief as the Court may deem just and appropriate.

Respectfully submitted,

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